## Food and Drug Administration, HHS

## §177.1380 Fluorocarbon resins.

Fluorocarbon resins may be safely used as articles or components of articles intended for use in contact with food, in accordance with the following prescribed conditions:

- (a) For the purpose of this section, fluorocarbon resins consist of basic resins produced as follows:
- (1) Chlorotrifluoroethylene resins produced by the homopolymerization of chlorotrifluoroethylene.
- (2) Chlorotrifluoroethylene-1,1-difluoroethylene copolymer resins produced by copolymerization of chlorotrifluoroethylene and 1,1-difluoroethylene.
- (3) Chlorotrifluoroethylene-1,1-difluoroethylene-tetrafluoroethylene co-polymer resins produced by co-polymerization of chlorotrifluoroethylene, and tetrafluoroethylene.
- (4) Ethylene-chlorotrifluoroethylene copolymer resins produced by copolymerization of nominally 50 mole percent of ethylene and 50 mole percent of chlorotrifluoroethylene. The copolymer shall have a melting point of 239 to 243 °C and a melt index of less than or equal to 20 as determined by ASTM Method D 3275-89 "Standard Specification for E-CTFE-Fluoroplastic Molding, Extrusion, and Coating Materials," which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the American Society for Testing and Materials, 1916 Race St., Philadelphia, PA 19013, or may be examined at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.
- (b) Fluorocarbon resins that are identified in paragraph (a) of this section and that comply with extractive limitations prescribed in paragraph (c) of this section may be used as articles or components of articles intended for use in contact with food as follows:
- (1) Fluorocarbon resins that are identified in paragraphs (a)(1), (a)(2), and (a)(3) of this section and that comply only with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used when such use is limited to articles or components of articles that are intended

for repeated use in contact with food or that are intended for one-time use in contact with foods only of the types identified in §176.170(c) of this chapter, table 1, under Types I, II, VI, VII-B, and VIII.

- (2) Fluorocarbon resins that are identified in paragraph (a)(4) of this section and that comply with the extractive limitations prescribed in paragraphs (c)(1) and (c)(2) of this section may be used only when such use is limited to articles or components of articles that are intended for repeated use in contact with food.
- (3) In accordance with current good manufacturing practice, those food-contact articles intended for repeated use shall be thoroughly cleansed prior to their first use in contact with food.
- (c) Extractives limitations are applicable to the basic resins in the form of pellets that have been ground or cut into small particles that will pass through a U.S. Standard Sieve No. 6 and that will be held on a U.S. Standard Sieve No. 10.
- (1) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.
- (2) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of 50 percent (by volume) ethyl alcohol in distilled water at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.003 percent by weight of the resins.
- (3) A 100-gram sample of the resin pellets, when extracted with 100 milliliters of n-heptane at reflux temperature for 8 hours, shall yield total extractives not to exceed 0.01 percent by weight of the resins.

[42 FR 14572, Mar. 15, 1977, as amended at 57 FR 185, Jan. 3, 1992]

## § 177.1390 Laminate structures for use at temperatures of 250 °F and

(a) The high-temperature laminates identified in this section may be safely used for food contact at temperatures not exceeding 135  $^{\circ}$ C (275  $^{\circ}$ F) unless otherwise specified. These articles are layered constructions that are optionally bonded with adhesives. The interior